

Amendment
Application of MEUNIER et al.
Appln. No. 10/542,607
Conf. No. 7312
Attorney Docket No. 802220-0021US

REMARKS

Reconsideration and allowance of the above-identified application are respectfully requested in view of the amendments and remarks made herein.

Pending claims:

Upon entry of this amendment, claims 1-10 are pending. No claims have been added or cancelled, and claims 1 and 10 are in independent form.

Petition for extension of time:

In accordance with 37 C.F.R. § 1.136(a), Applicants hereby petition for an extension of time sufficient to permit entry of the present amendment. The Petition Fee under 37 C.F.R. § 1.17(a) should be charged to Deposit Account No. 502-927.

Formal issues:

1. Priority:

The Examiner's comments in the pending Official Action regarding a possible priority claim based on PCT/FR/03929 are not clearly understood.

Applicants respectfully point out that the present US application is a national phase entry of PCT/FR/03929, filed on December 29, 2003, which in turn claims priority from French National Patent Appln. No. 03-00555, filed on January 20, 2003.

In accordance with MPEP § 1893.03(c), the benefit of priority was appropriately claimed in the international stage procedure relative to PCT/FR/03929.

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In addition, the priority claim was repeated in the Application Data Sheet filed in the Patent Office upon entering US national stage. This Application Data Sheet is date stamped by the Patent Office on July 18, 2005.

Finally, the Examiner's attention is respectfully directed to MPEP § 1893.03(c), part IV, which states:

Note: a national stage application submitted under 35 U.S.C. 371 may not claim benefit of the filing date of the international application of which it is the national stage since its filing date is the date of filing of that international application. See also MPEP § 1893.03(b). Stated differently, since the international application is not an earlier application (it has the same filing date as the national stage), a benefit claim under 35 U.S.C. 120 in the national stage to the international application is inappropriate and may result in the submission being treated as an application filed under 35 U.S.C. 111(a). See MPEP § 1893.03(a). Accordingly, it is not necessary for the applicant to amend the first sentence(s) of the specification to reference the international application number that was used to identify the application during international processing of the application by the international authorities prior to commencement of the national stage. (Emphasis added.)

In view of the foregoing, all requirements for correctly claiming priority are believed to have been met. Should the Examiner continue to believe otherwise, clarification is respectfully requested.

2. Requirement for drawings under 37 C.F.R. § 1.81(c):

The requirement for drawings under 37 C.F.R. § 1.81(c), as imposed by the Examiner in the present Official Action is not understood.

The Examiner is respectfully reminded that the present application as filed already contains Figures 1-3. In addition, the Examiner has not identified any claimed subject matter ostensibly admitting of illustration without such subject matter being illustrated in accordance with 37 C.F.R. § 1.81(c). As such, Applicants respectfully traverse this requirement. Should the Examiner continue to feel that this objection is valid, clarification is respectfully requested.

Patentability:

1. Rejection under 35 U.S.C. § 102(e) in view of Bartish:

Claims 1 and 3 have been rejected under 35 U.S.C. 102(e) as being anticipated by Bartish.

As amended, independent claim 1 recites implantable cells [that are] physiologically effective for regenerating an intervertebral disk. See, for example, paragraph 0010 of the present application.

In paragraph 0121 of Bartish (cited by the Examiner), Bartish discloses chambers 151, 153 “adapted to hold bone graft material therein and promoting bone fusion therethrough.” In paragraphs 0152-0155 of Bartish, various examples of the bone graft material are disclosed, including, in pertinent part “concentrated osteogenetic materials such as autologous mesenchymal stem cells (MSCs) or recombinant MSCs...” (Emphasis added.) See paragraph 0155 of Bartish.

In short, Bartish is completely focused on the promotion of bone fusion, including by means of providing a bone graft (i.e., a bone producing) material such as osteogenetic autologous mesenchymal stem cells. Bartish does not teach or suggest

the use of implantable cells that are physiologically effective for regenerating an intervertebral disk, as in claim 1.

In addition, promoting bony material formation (as suggested by Bartish) in an intervertebral disk is directly contrary to the notion of regenerating a disk, in that an intervertebral disk requires that at least a part thereof be soft and resilient. See, for example, paragraph 0002 in the present application.

In view of the foregoing, independent claim 1 (and dependent claim 3 depending therefrom) is patentable over Bartish.

2. Rejection under 35 U.S.C. 103(a) with respect to Taylor and Burg:

Claims 1, 2, and 5-10 were rejected under 35 U.S.C. § 103(a) as being obvious over Taylor in view of Burg.

As acknowledged by the Examiner, Taylor does not teach or suggest the presence and/or use of cells that are physiologically effective for regenerating an intervertebral disk. Taylor merely describes a certain type of interspinous prosthesis.

Separately, Burg makes a single, vague reference to the fact that the “present invention can also be used in correcting defects in, e.g., bones and spinal discs.” (Paragraph 0047.) It should be noted that “correcting defects” is considerably more vague than “regeneration” as such.

Even if it were conceded that Burg could be construed to disclose an injectable cell composition, one of ordinary skill would be at best left with two independent pieces of technical knowledge, with no motivation or suggestion in the prior art to combine them so as to arrive at the claimed invention. For example, there is no

recognition in the prior art of record, unlike in the present application, that mechanical stresses between adjoining vertebrae can retard or comprise disk regeneration as provided by cell treatment as claimed. See, for example, paragraphs 0006, 0008, and 0010 of the present application.

As such, even if Taylor and Burg do teach individually that which the Examiner alleges, the references, alone or in combination, do not motivate one of ordinary skill to combine their teachings to arrive at the presently claimed invention. In fact, the only basis for making the proposed combination is the conclusory statements of the Examiner, which have no apparent basis in the prior art.

In view of the foregoing, claims 1 and 10 are patentable over the prior art, as are the respectively claims depending directly or indirectly from claim 1.

3. Rejection under 35 U.S.C. § 103(a) with respect to Bartish and Trieu:

Claim 4 has been rejected under 35 U.S.C. § 103(a) as being obvious over Bartish in view of Trieu.

Trieu adds no teaching or disclosure to that of Bartish that overcomes the deficiencies of Bartish relative to independent claim 1. Namely, Bartish fails to teach or suggest implantable cells that are physiologically effective for regenerating an intervertebral disk. In fact, as previously indicated, Bartish is particularly limited to providing bone graft (i.e., bone producing) materials for inducing bony fusion. Although Trieu may indeed teach that which is alleged by the Examiner, there is no motivation or other reason in the relied upon prior art to substitute embryonic stem

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cells according to Trieu for the bone graft material of Bartish, except for the Examiner's conclusory statements that such would have been obvious.

Accordingly, independent claim 1 remains patentable over the combination of Bartish and Trieu, and therefore dependent claim 4 is patentable at least by its dependence from claim 1.

Conclusion:

In view of the foregoing, favorable reconsideration on the merits is solicited. Should the Examiner feel a further telephonic discussion regarding this application would be useful, he is invited to contact Applicant's undersigned attorney by email or by fax so that the necessary arrangements can be made.

Respectfully submitted,

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